MAY - 8 2001

K011097

XI. SUMMARY OF SAFETY AND EFFECTIVENESS

Product:
QuickVue® Dipstick Strep A

Manufacturer:
Quidel Corporation
10165 McKellar Court
San Diego, California 92121
U.S.A.

Device Classification:
Streptococcus spp. serological reagents
866.3740
Class I

Intended Use:
The QuickVue Dipstick Strep A is a sensitive immunoassay for the qualitative detection of Group A Streptococcal antigen from throat swab specimens or confirmation of presumptive Group A Streptococcal colonies from culture. This test is to be used to aid in the diagnosis of diseases caused by Group A *Streptococcus*.

Physiologic Basis for the Test:
Group A *Streptococci* are organisms that typically cause illness such as tonsillitis, pharyngitis and scarlet fever. If untreated, these infections can lead to complications such as rheumatic fever and glomerulonephritis.

Principle of the Test:
To perform the test, a throat swab specimen is collected. The specimen is subjected to a chemical extraction of a carbohydrate antigen unique to Group A *Streptococcus* with Reagents A and B. The Dipstick is then placed in the extracted sample and the sample flows by capillary action through the test strip. If the patient sample contains Group A Streptococcal antigen, a pink Test Line and a blue Control Line will form to indicate a positive result. If Group A Streptococcal antigen is not present in the sample, only the blue Control Line will form to indicate a negative result.

Safety and Effectiveness:
Numerous studies were undertaken to document the performance characteristics and the substantial equivalence of the test to other commercially available products for qualitative detection of Group A Streptococcal antigen. These studies included the following:

1. The test was shown to be similar to other commercially distributed tests in terms of features and intended use.

2. The test was shown to have excellent intra- and inter-assay precision.

3. Lot-to-lot consistency analyses showed the test to be reproducibly manufacturable.

4. Common bacterial microorganisms and potentially interfering substances were shown not to interfere with the test's performance.

5. A multi-center evaluation of the test was conducted to determine the clinical performance of the test relative to culture techniques to establish substantial equivalence.

6. Physicians' Office studies were conducted to demonstrate that physician office personnel with diverse educational backgrounds and work experience could perform the test accurately and reproducibly.

Conclusion:
These studies demonstrated the substantial equivalence of the QuickVue Dipstick Strep A test to currently marketed devices which have been reviewed and cleared through the 510(k) notification process. They further demonstrated the suitability of the product for professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 8 2001

Ms. Robin Weiner
Vice President
Clinical and Regulatory Affairs
Quidel Corporation
10165 McKeller Court
San Diego, CA 92121

Re: 510(k) Number: K011097
Trade/Device Name: QuickVue® Dipstick Strep A
Regulation Number: 866.3740
Regulatory Class: I
Product Code: GTY
Dated: April 10, 2001
Received: April 11, 2001

Dear Ms. Weiner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

XIII. INDICATIONS FOR USE (Separate Page):

Page 1 of 1

510(k) Number (if known): K011097

Device Name: **QuickVue® Dipstick Strep A**

Indications for Use:

The QuickVue Dipstick Strep A is intended for the qualitative detection of Group A Streptococcal antigen directly from throat swab specimens or confirmation of presumptive Group A Streptococcal colonies from culture. The test is intended for use by healthcare professionals.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use _____
(Per 21 CFR 801.109)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011097